Spire Biomedical, Inc. • One Patriots Park • Bedford, MA 01730-2396
(781) 275-6001 • (781) 275-6010 fax

SECTION 7

OCT 11 2002

510(K) Summary

Percutaneous insertion kit is designed to provide physicians with a dual wire technique for use with Spire Biomedical, Inc.'s Pourchez Retro™ and XpressO™ catheters only.

Date: September 27, 2002

Submitter:
Spire Biomedical, Inc.
One Patriots Park
Bedford, MA 01730-2396
Phone: (781) 275-6001
Fax: (781) 275-6010

Contact Person:
Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
Phone: (781) 275-6001 x221
Fax: (781) 275-6010
e-mail: dfickett@spirecorp.com

Device Names:

Trade Name: SafeTrac Dual Wire Insertion Kit

Common Name: Vessel dilator

Classification Name: Blood access device and accessories

Legally Marketed Devices to Which Substantial Equivalence is Claimed:

1) Spire Biomedical, Inc. Pourchez RetrO and XpressO Twin Lumen Chronic Hemodialysis Catheters with Separated Tips (K013160, K021212 & K022000) similar kit accessories used for percutaneous insertion of these catheters.
2) Medtronic Model 9210 Delivery Catheter per K013963 for the percutaneous insertion technique only.

Device Description: The "SafeTrac Dual Wire Insertion Kit" provides an alternative method for chronic hemodialysis catheter placement by using an over the wire tec hnique dilating and inserting either the Pourchez RetrO and XpressO catheters over a guidewire percutaneously. The introducers consist of a plastic hub attached to a plastic cannula. The distal end of the cannula is thermally tapered to assist dilation. The hub proximal end has a female luer lock configuration. An optional hub collar may be used to attach the dilator to the catheter. The kits come with two guidewires, two 5F dilators, a 6F, 14F and 16F sheath/dilators in five different lengths. Each kit consists are to be supplied sterile and for single use only. The kits are to be sold in boxes of five.

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510(K) Summary
(Continued)

SafeTrac Dual Wire Insertion Kit for use with Spire Biomedical, Inc.'s Pourchez RetrO and XpressO Catheters only.

Intended Use

Percutaneous insertion kit is designed to provide physicians with a dual wire technique for use with Spire Biomedical, Inc.'s Pourchez Retro™ and XpressO™ catheters.

Technological Characteristics Comparison to Predicate Devices

The "SafeTrac Dual Wire Insertion Kit" consists of two 0.038" guidewires, two 5 Fr dilators, a 6 Fr sheath/dilator, 14 Fr and 16 Fr dilator cleared for commercial sale by per 510(K) Premarket Notifications or classified as a preamendment device.

Biocompatibility testing of these devices was established and documented per the original manufacturer's Premarket Notification 510(K) prior to commercial sale.

Performance Data

There are no performance criteria for the devices to be included with Spire Biomedical, Inc.' SafeTrac Dual Wire Insertion Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Mr. Donald Fickett
Director of RA/QA
Spire Biomedical, Inc.
One Patriots Park
BEDFORD MA 01730-2396

Re: K022620
Trade/Device Name: SafeTrac Dual Wire Insertion Kit (Sheathless Accessory Kit)
Models XRIK24, 28, 32, 36, 40 and XRIKRT
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: 78 FKA
Dated: August 6, 2002
Received: August 7, 2002

Dear Mr. Fickett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022620

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APPENDIX B – Indications for Use Statement

Device Name: SafeTrac Dual Wire Insertion Kit

Indications for Use: Percutaneous insertion kit designed to provide physicians with a dual wire technique for use with Spire Biomedical, Inc.'s Pourchez XpressO™ and Pourchez RetrO™ catheters only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022620